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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,341	04/13/2000	ERIC GORDON MAHERS	602-1466	4968

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MILLER, MARTIN E

ART UNIT	PAPER NUMBER
2623	

DATE MAILED: 12/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/462,341	MAHERS ET AL.
	Examiner Martin Miller	Art Unit 2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 April 2000 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Priority

1. The Examiner acknowledges that this application is a 371 of PCT/GB98/01916 claiming priority to United Kingdom application 9714347.3 filed July 9, 1997.

Response to Amendment

2. The preliminary amendment filed April 13, 2000 has been entered into the file and the claims amended accordingly.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "readable information" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 refers to "machine readable information" not readable information.

With respect to claim 12, the camera means recites a limitation of " imaging a plate", it is unclear whether the plate is the AST plate or another plate. Appropriate correction is required.

Claim 13 recites the limitation "the disk" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the disk image" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

As per claim 14, it recites the term " 'expert system' " with single quotes around it; this seems to indicate that the applicant is not sure if his invention utilizes an expert system or the extent of the expert system being used.

Additionally, claims 16 and 17 are rejected due to their dependence on rejected claims 13.

Regarding claim 18, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Applicant uses the phrase "such as a disk" in line 4 of limitation b). In addition, the claim refers to "this" in the second to last line of limitation b), it is unclear whether applicant is referring to the reading direction or the device, appropriate clarification is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 5-7, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berndt, US 5595708.

As per claim 1, Berndt teaches:

a carrier device (fig. 7, element 32);

the device releasably carrying an antibiotic (typically vials contain blood being examined for biological activity, col. 3, ll. 43-51) related to the test, and bearing machine readable information (barcode, Abstract) concerning the antibiotic, wherein the device also includes orientation means (CCD camera and the barcodes 234 and 212 of figure 9) image for enabling an image analyzer (col. 9, ll. 39-40, col. 10, ll. 15-29) to determine the optimal reading direction of the readable information. The examiner is interpreting "optimal reading direction" to mean barcode in the proper orientation to be read.

Berndt does not specifically teach that his system is used with an antibiotic susceptibility test (AST), however, it would have been obvious to one of ordinary skill in the art to use sample marking system of Berndt to keep track of biological samples to insure that the determined results of the test are tied to a particular sample and to avoid a misidentification of either the vial or test results. Additionally, Berndt's system assures that the vial will automatically be in the correct reading position for the CCD.

As per claim 2, Berndt teaches:

orientation means comprises means other than said machine readable information (reference indicia, col. 2, ll. 36-40).

As per claim 3, Berndt teaches;

in which the orientation means is separate from said machine readable information (fig. 9 element 234 versus element 212).

As per claim 5, Berndt does not teach an AST disk; however, Berndt teaches imaging a vial, which is the functional equivalent of an AST disk. Therefore, it would have been obvious to one of ordinary skill in the art to use the imaging system of Berndt that operates upon smaller indicia than what could be placed upon a disk because the greater resolution required of Berndt would easily perform the same function on a larger barcode identifier.

As per claim 6, Berndt teaches:

the orientation means comprises an arrangement of information presented on the device surface (reference indicia fig. 9, element 234), in addition to the readable information (fig. 9, element 212).

As per claim 7, Berndt teaches:

in which said orientation means comprises linearly-arranged information (fig. 9, element 234 comprises linearly arranged information).

As per claim 11, Berndt teaches:

which said machine readable information or character code identifies said substance and/or its concentration (required writing, col. 1, ll. 34-36 and col. 10, ll. 26-30). It would have been obvious to one of ordinary skill in the art that barcodes can contain a large amount of data including and such items as a station numbers and data pertaining to the device at that location.

8. Claims 4, 8-10, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brendt, further in view of Wevelslep et al. (hereinafter Wevelslep), US 4403339.

As per claim 4, Brendt teaches machine-readable codes not character codes. However, Wevelsiek teaches reading character codes, Wevelsiek teaches:

in which the machine readable information comprises a code of one or more characters (col. 7, ll. 44-46), whereby an image analyzer comprising code reading means, can determine the orientation of the code (col. 8, ll. 9-16, col.)

Brendt teaches:

, using the orientation means, and can adjust the orientation of the code (col. 9, ll. 39-40, col. 10, ll. 14-15), or an image thereof, to bring the perceived orientation into alignment with that necessary for proper reading of the code (col. 10, ll. 27-33).

It would have been obvious to one of ordinary skill in the art to use the character codes, which are human-readable, of Wevelsiek in place of the only machine-readable codes of Brendt so that the user can quickly read the label and verify the location if one of the vials gets mispositioned or misplaced.

As per claim 8, Wevelsiek teaches:

wherein said linearly-arranged information (fig. 2, element 75) is parallel to the optimal reading direction of the readable information (fig. 2, element 70).

As per claim 9, Wevelsiek teaches:

wherein said linearly-arranged information is a printed line or lines, printed below or above the readable information (fig. 2, element 75).

As per claim 10, Wevelsiek teaches:

wherein said orientation means comprises an underline printed beneath the character code (fig. 2, element 75).

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As per claim 18, Berndt does not specifically teach a culture medium, but he does teach a blood vial used for detecting the presence of bacterial growth (first sentence of abstract). Berndt teaches:

- a) camera means for viewing the medium (vial) (CCD camera, col. 10, ll. 9-11);
- b) electronic information processing means (system controller, fig. 7, element 98, col. 10, ll. 4-6), linked to said camera (col. 10, ll. 13-16), programmed or trained to interpret any region visibly altered micro-organism growth (bacterial growth) in the vicinity of a susceptibility testing device, such as a disk, present on the culture medium (col. 10, ll. 37-47).

Berndt does not specifically teach reading a character code, but he teaches processing all the information of a machine-readable code. Therefore, with respect to a machine-readable code, Berndt teaches:

wherein said processing means is also programmed or trained to read a code on the device indicative of the susceptibility reagent in the device and to interpret orientation means incorporated in or on the device by which optimal reading direction of the code can be recognized, and to adjust as necessary the actual reading direction to bring this into line with the actual orientation of the code on the device (col. 10, ll. 14-17).

With respect to determining the orientation of a character code, Wevelsiek cures the deficiency of Berndt by using character codes as his machine-readable indicia (fig. 2, element 71). It would have been obvious to one of ordinary skill in the art to use the character code of Wevelsiek to label a vial to improve the labeling security of Berndt by using a code that is human-readable so that if a vial does get mispositioned it can be easily identified by a user.

Additionally, the user would not have to use a barcode scanner to determine where the vial should go in the device.

9. Claims 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graessle et al., (Hereinafter Graessle), US 5573950 and Tsuchiya et al., (hereinafter Tsuchiya), US 5134272.

As per claim 12, neither Graessle nor Tsuchiya does not specifically teach an AST plate; however, Graessle teaches using a disposable microorganism culturing device (col. 5, ll. 18-21) which is equivalent to a AST. Therefore Graessle teaches:

Support means for supporting an AST plate (fig. 2, cassette 20, col. 4, ll. 60-65); camera means for imaging a plate supported by said support means (CCD image sensor, col. 8, ll. 5-7); and

electronic information processing means, preferably a neural net, linked to said camera means(microprocessor, col. 8, l. 5-7), programmed or trained to locate ("incrementally advance substrates through the imaging position", col. 8, ll. 18-20) an AST carrier device on said plate from among the plurality of AST carrier devices,

However, Graessle does not teach aligning the perceived barcode image into the proper alignment. But, Tsuchiya teaches:

identify orientation means on the located carrier device (fig. 2a) , and rotate (Tsuchiya teaches that he derives a position coordinate representing a central axis and a center position, col. 2, l. 67-col. 3, l. 5) the perceived image of the located device as required so that the perceived image of the located device as required so that the perceived image of a multi-character (fig. 2(a), element A, shows multi-character code) code printed on the device is brought into

alignment (decoding is done on the pixel values extending along the determined central axes, col. 3, ll. 7-8) with a proper reading direction for the code, and reading the code (col. 3, ll. 5-10).

It would have been obvious to one of ordinary skill in the art to use the image processing features of Tsuchiya to correct for misaligned barcode images so that the system does not have to be manually adjusted or mechanically adjusted for the barcode to be decoded in the automated scanning system of Graessle.

As per claim 13, Tsuchiya teaches:

a visible characteristic of the zone of inhibition, if any, surrounding the disk (fig. 2d, because the specification states that the inhibition zone is the darkest part of the image, p. 13, ll. 15-20). Since there is a lack of antecedent basis for the disk, the examiner is interpreting the disk to be the multi-character code.

As per claim 15, Graessle teaches:

displaying means for displaying the disk image (col. 8, ll. 40-43). The CCD image is provided to a computer it is well known that a monitor connected to the computer can then display such imagery. This would have been obvious to one of ordinary skill in the art.

As per claim 16, Tsuchiya teaches:

wherein the diameter of the zone of inhibition is determined (col. 7, ll. 49-53). Tsuchiya teaches that the center coordinates of the black region is determined, it would have been obvious to one of ordinary skill in the art to divide the diameter by 2 to determine the center position of the black region.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graessle and Tsuchiya, further in view of Rutenberg, US 4965725.

As per claim 14, Graessle teaches:

wherein the electronic information processing means includes or is linked (col. 8, ll. 42-44) to a database for analysis. But neither Graessle nor Tsuchiya teach an expert system.

However, Rutenberg teaches:

an expert system comprising a database of AST characteristics of known organisms (col. 1, ll. 46-49).

It would have been obvious to one of ordinary skill in the art to use a expert system to analyze the image pattern provided by Graessle to combine the experience of a human technologist and trainable artificial intelligence.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graessle and Tsuchiya, further in view of Wevelsiek.

As per claim 17, neither Graessle nor Tsuchiya teaches an underline beneath the multi-character code. However, Wevelsiek teaches:

wherein the system is programmed or trained to identify orientation means which comprises an underline printed beneath the multi-character code (fig. 2, element 75). It would have been obvious to one of ordinary skill in the art to use the underline of Wevelsiek in the imaging system of Graessle and Tsuchiya to provide an additional means to insure the proper alignment of the code being read by Tsuchiya and Graessle.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following U.S. patent(s) refer(s) to detecting and identifying biological data: Braier et al., 5694478, Hochman, 6096510, Cabib et al., 5991028 and 5784162, Wilkins,

5290701, Hemstreet, III et al., 5733721, Brendt, 5397709. The following U.S. patent(s) refer(s) to data symbol decoding: Domanik, 5798514, Liu, 5764798, Windel et al., 5734723, and Maltsev, 6064763.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin Miller whose telephone number is (703) 306-9134. The examiner can normally be reached on Monday-Friday, Maxi-flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9314 for regular communications and (703) 872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

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December 8, 2002



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